

§ 821.2

provide FDA with a complete set of its tracking records and information. However, if a person ceases distribution of a tracked device but continues to do other business, that person continues to be responsible for compliance with this part unless another person, affirmatively and in writing, assumes responsibility for continuing the tracking of devices previously distributed under this part. Further, if a person subject to this part goes out of business completely, but other persons acquire the right to manufacture or distribute tracked devices, those other persons are deemed to be responsible for continuing the tracking responsibility of the previous person under this part.

EFFECTIVE DATE NOTE: At 67 FR 5951, Feb. 8, 2002, § 821.1 was amended by revising paragraphs (a) and (b), by removing paragraph (c), and by redesignating paragraphs (d) and (e) as paragraphs (c) and (d), effective May 9, 2002. For the convenience of the user, the revised text is set forth as follows:

§ 821.1 Scope.

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act), which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences; or the device is intended to be implanted in the human body for more than 1 year; or the device is a life-sustaining or life-supporting device used outside a device user facility. A device that meets one of these criteria and is the subject of an FDA order must comply with this part and is referred to, in this part, as a "tracked device."

(b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer's device track-

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ing effort, the legal responsibility for complying with this part rests with manufacturers who are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

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§ 821.2 Exemptions and variances.

(a) A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

(1) The name of the device and device class and representative labeling showing the intended use(s) of the device;

(2) The reasons that compliance with the tracking requirements of this part is unnecessary;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that an effective tracking system is in place; and

(4) Other information justifying the exemption or variance.

(c) An exemption or variance is not effective until the Director, Office of Compliance and Surveillance, CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

(d) For petitions received under this section before August 29, 1993, FDA will, within 60 days, approve or disapprove the petition or extend the effective date of this part for the device that is the subject of the petition. Any extension that FDA grants to the effective date will be based upon the additional time FDA needs to complete its review of the petition.

[58 FR 43447, Aug. 16, 1993, as amended at 59 FR 31138, June 17, 1994]

EFFECTIVE DATE NOTE: At 67 FR 5951, Feb. 8, 2002, § 821.2 was amended by removing paragraph (d), effective May 9, 2002.